South Dakota Medicare Rural Hospital Flexibility Program

(FLEX Program)

RURAL HEALTH PLAN

South Dakota Department of Health
Division of Health Systems Development and Regulation
Office of Rural Health

November 2008

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Doneen B. Hollingsworth, Secretary of Health

Pierre, South Dakota
November 2008
(This edition supersedes the editions published in April 1998, November 2000, May 2002, March 2004, and May 2006)

FORWARD

The South Dakota Rural Health Plan is to be used by the State of South Dakota in administering the Medicare Rural Hospital Flexibility Program (Flex Program) pursuant to section 4201 of the Balanced Budget Act of 1997 (Public Law 105-33) and amendments made thereto. The points of contact for the South Dakota Flex Program Plan are the following:

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A. INTRODUCTION

1. Background

The Medicare Rural Hospital Flexibility Grant Program (Flex Program) was authorized by section 4201 of the Balanced Budget Act of 1997 (BBA), Pub. L. 105-33 and was reauthorized by Section 405 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173. The program is an outgrowth of the Montana Medical Assistance Facility (MAF) Demonstration and the Essential Access Community Hospital/Rural Primary Care Hospital (EACH/RPCH) programs. The Flex Program is an ideal mechanism for improving and sustaining access to appropriate healthcare services of high quality in rural America. This program is administered federally by the Heath Resources and Services Administration - Office of Rural Health Policy. In South Dakota, the state program is administered by the South Dakota Department of Health – Office of Rural Health.

The Federal Office Rural Health Policy (ORHP) provides Flex Program grant funds to states for the development and implementation of State Rural Health Plans (SRHP). South Dakota's first SRHP was submitted to and approved by the Centers for Medicare and Medicaid Services (CMS) in 1998 and the first grant was for the State Flex Program in Fiscal Year 1999. Additionally, the South Dakota Office of Rural Health has received funding for its State Flex Program each year since FY 1999

2. Purpose

Since the first SRHP was published, updated editions were published in 2000, 2002, 2004, and 2006. For each of these editions – and this one, the goal is to provide clear policy direction through development, revision and implementation of one central document that can be readily accessed by providers and the public. For this central document, implementation plans to complete activities in the following five program goals established by ORHP will be presented:

1. Designation of Critical Access Hospitals (CAH) in the State.
2. Development and Implementation of Rural Health Networks.
3. Support of existing CAHs and Eligible Hospitals.
4. Improvement and Integration of Emergency Medical Services.
5. Improving Quality of Care

3. Method

Throughout the State Flex Program, ORH relies on input from stakeholders for planning and implementing activities. The primary stakeholders ORH collaborates with include:

1. The South Dakota Critical Access Hospitals
2. South Dakota Association of Health Care Associations (state hospital association)
3. South Dakota Foundation for Medical Care (QIO)
4. South Dakota Department of Health – Office of Licensure and Certification
5. South Dakota Department of Health – Office of Public Health Preparedness

6. South Dakota Department of Public Safety – Office of Emergency Medical Services
7. The Avera, Regional, and Sanford Health Systems

In addition to receiving input from stakeholders during planning meetings and conference calls, ORH collected information regarding the five program goals from Critical Access Hospitals through a survey conducted via Survey Monkey during the spring of 2008. A copy of this survey is in Appendix A. Thirty-three of the state's 37 CAHs completed this survey for a response rate of 89 percent. Results from this survey related to the specific goals will be provided as each goal is discussed throughout this SRHP.

B. DESIGNATION OF CRITICAL ACCESS HOSPITALS

1. Current Condition

The Flex Program helps sustain the rural healthcare infrastructure, with the Critical Access Hospital (CAH) as the hub of an organized system of care. As a CAH, rural hospitals receive 101 percent reimbursement for acute inpatient and outpatient services they provide to Medicare beneficiaries. A hospital must meet the following criteria to be designated a CAH:

- Be located in a state that has established a State Flex Program (as of December 2007, only Connecticut, Delaware, Maryland, New Jersey, and Rhode Island did not have such a program);
- Be located in a rural area or be treated as rural under a special provision that allows qualified hospital providers in urban areas to be treated as rural for purposes of becoming a CAH;
- Furnish 24-hour emergency care services, using either on-site or on-call staff;
- Provide no more than 25 inpatient acute care beds (in South Dakota, no more than 15 of these can be swing beds);
- Have an average annual length of stay of 96 hours or less; and
- Be located either more than 35 miles from the nearest hospital or CAH or more than 15 miles in areas with mountainous terrain or only secondary roads, or be State certified as of December 31, 2005 as a "necessary provider" of health care services to residents in the area.

Currently, South Dakota has 37 certified CAHs and one designated with a pending certification. The table below lists the current CAHs and the rural hospitals that are eligible through the proximity statute or the previous necessary provider provision. After the Sisseton hospital's certification is complete, all the small rural hospitals in state that meet the proximity statute will be certified CAHs.

Hospital Name	City	Certification Date	CAH Status	Licensed Beds	Type of Eligibility
Faulkton Area Medical Center	Faulkton	03/01/1998	Certified	12	Statute
Platte Community Memorial Hospital	Platte	04/01/1998	Certified	15	Necessary Provider
Douglas County Memorial Hospital	Armour	06/01/1998	Certified	11	Necessary Provider
Eureka Community Hospital	Eureka	06/01/1998	Certified	6	Necessary Provider
Burke Community Memorial Hospital	Burke	07/01/1998	Certified	16	Necessary Provider
Gettysburg Medical Center	Gettysburg	07/01/1998	Certified	10	Necessary Provider
Sanford Deuel County Medical Center	Clear Lake	10/01/1998	Certified	20	Necessary Provider
Flandreau Medical Center/Avera Health	Flandreau	01/01/1999	Certified	18	Necessary Provider
Sanford Hospital Webster	Webster	05/01/1999	Certified	25	Statute

Hospital Name	City	Certification Date	CAH Status	Licensed Beds	Type of Eligibility
Marshall County Memorial Hospital	Britton	03/01/2000	Certified	20	Statute
Freeman Community Hospital	Freeman	06/01/2000	Certified	25	Necessary Provider
Bennett County Community Hospital	Martin	07/01/2000	Certified	20	Statute
Redfield Community Memorial Hospital	Redfield	07/01/2000	Certified	25	Statute
Wagner Community Memorial Hospital	Wagner	07/01/2000	Certified	20	Necessary Provider
Landmann-Jungman Memorial Hospital	Scotland	10/01/2000	Certified	25	Necessary Provider
Bowdle Hospital	Bowdle	01/01/2001	Certified	12	Necessary Provider
Hans P Peterson Memorial Hospital	Philip	02/01/2001	Certified	18	Statute
Lead-Deadwood Regional Hospital	Deadwood	05/01/2001	Certified	18	Necessary Provider
Sturgis Regional Hospital	Sturgis	05/01/2001	Certified	25	Necessary Provider
Fall River Health Services	Hot Springs	06/27/2001	Certified	11	Necessary Provider
Custer Regional Hospital	Custer	07/01/2001	Certified	16	Necessary Provider
Avera Weskota Memorial Medical Center	Wessington Springs	10/01/2001	Certified	25	Statute
Milbank Area Hospital Avera Health	Milbank	01/01/2002	Certified	25	Necessary Provider
Mobridge Regional Hospital	Mobridge	01/01/2002	Certified	25	Statute
St. Michael's Hospital	Tyndall	03/01/2002	Certified	25	Necessary Provider
Pioneer Memorial Hospital	Viborg	03/01/2002	Certified	12	Necessary Provider
Madison Community Hospital	Madison	12/01/2002	Certified	25	Necessary Provider
Sanford Mid-Dakota Medical Center	Chamberlain	05/01/2003	Certified	25	Statute
Avera Dells Area Health Center	Dell Rapids	07/01/2003	Certified	23	Necessary Provider
De Smet Memorial Hospital	DeSmet	07/01/2003	Certified	17	Necessary Provider
Avera St. Benedict Health Center	Parkston	07/01/2003	Certified	25	Necessary Provider
Canton-Inwood Memorial Hospital	Canton	12/01/2003	Certified	22	Necessary Provider
Winner Regional Healthcare Center	Winner	04/01/2004	Certified	25	Necessary Provider
Huron Regional Medical Center	Huron	07/01/2004	Certified	25	Necessary Provider
Sanford Vermillion Medical Center	Vermillion	11/01/2004	Certified	25	Necessary Provider
Avera Hand County Memorial Hospital	Miller	07/01/2005	Certified	25	Statute
Avera Gregory Healthcare Center	Gregory	12/22/2005	Certified	25	Necessary Provider
Coteau Des Prairies Hospital	Sisseton	Pending	Designated	31	Statute

Hospital Name	City	Certification Date	CAH Status	Licensed Beds	Type of Eligibility
Avera St. Luke's Hospital	Aberdeen		Eligible	139	Statute
Brookings Hospital	Brookings		Eligible	49	Necessary Provider
Holy Infant Hospital	Hoven		Eligible	26	Necessary Provider
Avera Queen of Peace Hospital	Mitchell		Eligible	120	Necessary Provider
St. Mary's Hospital	Pierre		Eligible	60	Statute
Spearfish Regional Hospital	Spearfish		Eligible	40	Necessary Provider
Prairie Lakes Hospital	Watertown		Eligible	81	Necessary Provider
Sacred Heart Health Services	Yankton		Eligible	144	Necessary Provider

On the CAH Survey conducted during the spring of 2008, the hospitals were asked what the greatest impact they have experienced since converting to a CAH. In response to this, most of them stated financial stability. Additionally, many of the CAHs stated this financial stability has allowed them to concentrate on other areas, such as quality of care or staff recruitment and retention.

2. Future Plans

Goal: To assist frontier and rural communities by assessing community needs; examining the appropriateness of designation and conversion to the Critical Access Hospital model; and promoting awareness of the program statewide.

- Objective 1: To ensure the Coteau Des Prairies Hospital's CAH Certification is completed in a timely manor
    - Activity 1: Monitor the certification process and provide assistance as needed
        - Outcome Measure 1a: By January 1, 2009, South Dakota will have 38 certified CAHs
- Objective 2: To ensure statewide awareness of the Flex/CAH Program.
    - Activity 1: Promote Flex/CAH program activities through press releases and Office of Rural Health Listserv postings.
        - Outcome Measure 1a: # and topic for press releases and listserv postings.

C. DEVELOPMENT AND IMPLEMENTATION OF RURAL HEALTH NETWORKS

1. Current Condition

As part of the statutory designation process, all the state's CAHs have referral, transfer, transportation, and communication agreements with larger acute care hospitals and credentialing and quality assurance agreements with the state's quality improvement organization. Beyond this requirement, the South Dakota Flex Program develops rural health networks in all areas of the program. For example, to support existing CAHs, Flex funds are used to support local CAH projects that create networks. The table below lists the project types and number of networks developed from FY1999 to FY2007 when Flex funds were used to support projects submitted by CAHs in response to a request for proposal (RFP) the state Flex Program issues each year.

	Grant Year									
Project Type	FY1999	FY2000	FY2001	FY2002	FY2003	FY2004	FY2005	FY2006	FY2007	**Total**
HIT/EMR	1			1	2		4	3	1	**12**
Telehealth	1	1								**2**
Tele-School Health		1	1	1						**3**
Tele-Home Health		3	2	1		1				**7**
Tele-Radiology	1	4				1				**6**
Distance Learning	1	2	3	1		1	1		1	**10**
CAH/Community Wellness Ed						4	3		1	**8**
Medication Dispensing								2	1	**3**
Telepharmacy									1	**1**
Total	**4**	**11**	**6**	**4**	**2**	**7**	**8**	**5**	**5**	**52**

Furthermore, because the South Dakota Office of Rural Health and its State Flex Program are participants in several statewide initiatives, Flex funds are used to implement and/or support several collaborative projects. The key partners for the collaborative projects include the CAHs, the state hospital association, the quality improvement organization (QIO), the Avera, Sanford and Regional Health Care Systems, the Office of Emergency Medical Services, and other state and federal agencies. A comparison of how the state's collaborative projects match the Flex Program goal areas include:

Support of existing CAHs – The Office of Rural Health is part of a statewide Healthcare Workforce Initiative with the state Departments of Education and Labor and the Board of Regents. As part of this initiative, Flex funds are provided to healthcare providers to develop partnerships with local schools to encourage students to pursue healthcare careers. For this program, 10 projects/networks were developed each year in FY2004 and FY2005, 18 were developed in FY2006, and 20 were developed in FY2007.

Improvement and integration of EMS services – The Office of Rural Health has been part a collaborative effort to develop a statewide trauma system since 1995. A result of this effort was the passing of a bill during the 2008 South Dakota Legislative Session to establish a statewide

trauma system. The specific use of Flex funds to support this initiative will be described in the EMS Integration section of this plan.

Improving quality of care – In FY2003, a performance improvement strategic planning network began with the Office of Rural Health, the state's CAHs, the South Dakota Association of Healthcare Organizations (hospital association), the South Dakota Foundation for Medical Care (QIO), and the state's three healthcare systems as participants. As part of the implementation phase of this planning network, patient safety, and multi-state benchmarking sub-networks were also developed. Currently, all 37 of the state's CAHs participate in the patient safety collaborative and 34 of 37 participate in multi-state benchmarking project. The activities and goals for the PI planning and the sub-networks will be discuss further in quality of care improvement section of this plan.

On the CAH Survey conducted during the spring of 2008, the hospitals were asked to list their greatest network development needs for the next 3 to 5 years. In response to this question, health information technology and workforce development were the most common needs listed by the CAHs.

2. Future Plans

Goal: To develop sustainable local systems of care by developing networking arrangements that will enhance efficiencies and improve access to care.

- Objective 1: To develop networks involving CAHs that address safety net needs, concerns, or issues of vulnerable rural populations.

    - Activity 1: Per federal statutory and South Dakota application requirements (a copy of the state application form is in Appendix #), rural hospitals seeking CAH designation will have written agreements with other general acute care hospitals regarding patient referrals, patient transfers, patient transportation, and communications and written agreements with the QIO regarding credentialing and quality assurance.
        - Outcome measure 1a: # of CAHs designated with agreements on file.

- Objective 2: To annually support networks that address unmet community needs and expand access of health care services as identified by CAHs.

    - Activity 1: The South Dakota Flex Program's annual request for proposals (RFP) that is issued to CAHs will encourage the CAHs to partner with other healthcare providers and organizations to complete local projects.
        - Outcome Measure 1a: # and types of network projects funded.

- Objective 3: The South Dakota Flex Program will participate in collaborative efforts that address state and federal healthcare initiatives.

- Activity 1: The Flex Program will participate in the state's Healthcare Workforce Initiative by supporting a minimum of 10 collaborative projects annually between healthcare providers and local schools that encourage students to pursue health careers.
  - Outcome Measure 1a: # and types of collaborative projects funded.
- Activity 2: The Flex Program will continue to participate in the state's Trauma System Development Initiative.
  - Outcome Measure 2a: types of activities the state Flex Program and CAHs will participate regarding the Initiative.
- Activity 3: The Flex Program will continue to have all CAHs in the patient safety collaborative and will all of them in the benchmarking collaborative by FY2010.
  - Outcome Measure 3a: # of CAHs in the collaboratives.
- Activity 4: The Flex Program will implement collaborative efforts for future initiatives that match program goals.
  - Outcome Measure 4a: list of collaborative projects and a list partnering organizations.

D. SUPPORT OF EXISTING CAHS AND ELIGIBLE HOSPITALS

1. Current Condition

The methods the South Dakota Flex program use to support critical access hospitals and other rural providers include providing funding for local projects and healthcare provider recruitment, holding educational conferences, and conducting site visits. To fund local projects, a request for proposals is released each year to all the state's CAHs so they can develop proposals that address local needs. In addition to the collaborative projects listed in the Network Development Section of this plan, projects are also funded that involve only a single CAH, such as information systems and staff development projects. From FY1999 to FY2007, over $2.4 million in Flex funds have been distributed to support 108 projects through this RFP process. The total number of projects funded is not the primary purpose of this program, though. Instead, each project is evaluated regarding proposed outcomes, such as maintaining or improving healthcare access and/or improving quality of care.

The Health Professional Recruitment Incentive Program (HPRIP) and the Health Occupations for Today and Tomorrow (HOTT) are two programs that use Flex funds to assist healthcare providers (including CAHs and eligibles) to sustain a healthcare workforce. The HPRIP program provides a $5,000 incentive to health professionals after two years of service at a licensed healthcare facility or federally qualified healthcare center. Flex funds are used to pay 75 percent of the incentive for communities with less than 2,500 residents and 50 percent of the incentive for communities with 2,500 or more residents. In comparison, the HOTT Program was developed to encourage school aged children to pursue health careers. Under this program, Flex funds are used to provide $2,000 grants to providers for collaborative projects with local schools. As indicated in the Network Development Section of this plan, 58 projects were funded from FY2004 through FY2007.

Since the CAH program started, the Office of Rural Health has worked with the South Dakota Association of Healthcare Organizations (SDAHO) on an annual CAH Update Workshop. This workshop provides updates regarding the Flex Program at both the state and federal levels, plus education session, such as reimbursement or billing. In addition to the CAH Update, workshops are held on specific topics. For example, since FY2006, the Flex Program has worked with SDAHO, the QIO, and the state's three health systems on an annual fall workshop for the Rural Hospital Patient Safety Initiative. For this initiative, the state's 37 CAHs and two other rural hospitals receive tools to encourage a culture of safety from experts at the fall workshops and through quarterly conference calls.

The South Dakota Flex Program conducts site visits at approximately half the state's CAHs each year. The purpose of these visits is to evaluate projects supported with Flex and Small Rural Hospital Improvement Program (SHIP) Grant funds, to provide information to the hospitals regarding state and federal programs and initiatives, and to gage the needs of the hospitals and their communities. Because information is received from as well as shared with the hospital staff, site visits have inspired new programs and initiatives. For example, information gained from site visits contributed to the development of the South Dakota Healthcare Workforce Initiative and a CAH Leadership Development Program.

On the CAH Survey conducted during the spring of 2008, the hospitals were asked to list their most predominant current issue. In response to this question, workforce recruitment/retention and access to capital were most common issues listed. Additionally, the CAHs were asked to rate the benefit they receive from the approaches the Flex Program uses to provide support. Regarding the RFP Program, 29 CAHs provided a response. Of these 29, 16 reported receiving a substantial benefit, 11 reported receiving a moderate benefit, 1 reported receiving a limited benefit, and 1 reported no benefit. Regarding the HPRIP Program, 30 CAHs provided a response. Of these 30, 18 reported receiving a substantial benefit, 8 reported receiving a moderate benefit, 2 reported receiving a limited benefit, and 2 reported no benefit. Regarding the Annual CAH Update Workshops, 31 CAHs provided a response. Of these 31, 12 reported receiving a substantial benefit, 15 reported receiving a moderate benefit, 3 reported receiving a limited benefit, and 1 reported no benefit.

2. Future Plans

Goal: To support and sustain critical access hospitals; therefore, ensuring rural South Dakota residents have access to appropriate healthcare services.

- Objective 1: To assist CAHs with addressing needs by providing funding for local projects.
    - Activity 1: Will issue an annual request for proposals to solicit proposals from CAHs that develop sustainable local projects.
        - Outcome Measure 1a: # and types of projects funded
    - Activity 2: Will evaluate all projects funded.
        - Outcome Measure 2a: Will measure project impact, such as improved quality or efficiency.
        - Outcome Measure 2b: Will measure how easy the projects can be replicated
- Objective 2: To help sustain an adequate healthcare workforce to serve rural residents.
    - Activity 1: Through the Health Professional Recruitment Incentive Program (HPRIP) will assist communities with recruiting and retaining healthcare professionals.
        - Outcome Measure 1a: # and types of health professionals participating in HPRIP program and location
    - Activity 2: Will provide support to healthcare providers to develop projects with local schools that encourage K-12 students to pursue health careers.
        - Outcome Measure 2a: #, type, and location of projects funded and will determine if projects can be replicated
- Objective 3: Will work with partners to hold at least 2 workshops each year for CAHs.
    - Activity 1: Will work with SDAHO each year to hold the Annual CAH Update Workshop
        - Outcome Measure 1a: # of attendees, topics presented, attendee evaluations

- Activity 2: Will work with partners and CAHs to hold at least one workshop each regarding a relative issue or initiative, such as patient safety or healthcare workforce.
  - Outcome Measure 2a: Workshop topics, # of attendees, attendee evaluations

- Objective 4: Each South Dakota CAH will receive at least one site visit every two years

  - Activity 1: Will schedule site visits at half the state's CAHs each year.
    - Outcome measure 1a: Types of project evaluated and/or technical assistance provided

E. IMPROVOMENT AND INTEGRATION OF EMERCENY MEDICAL SERVICES

1. Current Condition

Since the FY2004 Application, the South Dakota Flex Program has been working towards the development of a statewide trauma system. In preparation for this, Flex funds have been use to provide Trauma Nurse Core Courses (TNCC) to CAH nurses and trauma facility reviews of CAHs. In 2006, Governor M. Michael Rounds appointed a Trauma System Development Steering Committee. Members of this committee include the Secretaries for the Departments of Health and Public Safety; trauma surgeons and nurses from the state's three hospital systems; Indian Health Services; and the state's hospital, medical and EMT associations. Office of Rural Health staff provided staff support and served on sub-committees for this Steering Committee. A primary responsibility of this Steering Committee was to draft legislation to establish a statewide trauma system. This legislation was introduced and passed during the January-February 2008 South Dakota Legislative Session. After this legislation passed, the role (and title) of the Steering Committee changed to a State Trauma Council. The primary role of this Council is to monitor the implementation of the statewide trauma system.

On the CAH Survey conducted during the spring of 2008, the hospitals were asked to list their greatest needs the next 3-5 years to improve EMS. The most common response to this question was EMS staff recruitment, retention, and training. Additionally, 25 of the 33 hospital administrators who completed the survey reported their facility had participated in the TNCC training. Of these, 10 reported the training was a substantial benefit to their facility, 10 reported it was a moderate benefit, 3 reported it was a limited benefit, and 2 report no benefit. Similarly, regarding the trauma facility reviews, 24 hospital administrators report a review was completed at their facility. Of these, 5 reported the review was a substantial benefit to their facility, 8 reported it was a moderate benefit, 6 reported it was a limited benefit, and 5 reported no benefit.

2. Future Plans

Goal: To improve the rural emergency medical services system by sponsoring initiatives in the areas of trauma, communications, training, and quality enhancement.

- Objective 1: The South Dakota Flex Program will support the activities of the State Trauma Council
    - Activity 1: The Flex Program will attend and provide staff support for Trauma Council meetings.
        - Outcome Measure 1a: # of meetings attended and specific duties staff perform to support the Trauma Council
    - Activity 2: Office of Rural Health Administrator will draft Administrative Rules for review and approval of the Trauma Council regarding trauma facility designation, transfer protocols, and trauma registry requirements.
        - Outcome Measure 2a: Administrative Rules are developed by July 1, 2009

- Objective 2: The South Dakota Flex Program will provided trauma-related training to CAH staff.

    - Activity 1: Will provide Trauma Nurse Core Courses (TNCC) to CAH nurses
        - Outcome Measure 1a: # of nurses trained, # of CAHs participating, and participate evaluations
    - Activity 2: Will promote Rural Trauma Team Development at CAHs
        - Outcome Measure 2a: Promotional activities completed and # of team developed

- Objective 3: The South Dakota Flex Program will assist CAHs determine the appropriate level of trauma facility each will have

    - Activity 1: Will provide trauma facility reviews and other assistance as needed to CAHs
        - Outcome Measure 1a: By January 1, 2012, all the hospitals in the state (including CAHs) will self-determine their level of designation for their facility.

F. IMPROVING QUALITY OF CARE

1. Current Condition

In June 2003, the South Dakota Flex Program held a statewide critical access hospital quality improvement conference to develop a QI strategic plan for the program. At this conference, a steering committee was developed to create a blue print for the strategic plan. The membership of this committee included the Flex Coordinator, CAH staff, the South Dakota Association of Healthcare Organizations (hospital association), the South Dakota Foundation for Medical Care (QIO), and the state's three healthcare systems. In August 2004, the results of this blue print were unveiled at a second statewide QI conference. This blue print included activities in two areas – administrative and clinical improvement. For the administrative portion, a leadership development program was initiated in January 2004. This is a three-year program that provides training to CAH department managers through site visits, conference calls, web-based training, and a shared resource library with leadership books and videos. To date, 20 CAHs have participated in the leadership program.

For clinical improvement, a Heartcare Collaborative was implemented with the Flex Program, the CAHs, and the QIO. For this collaborative, the CAHs provided data to the QIO as developed through the 7th (and later 8th) Scope of Work. This collaborative started in 2004 and lasted through 2006. In 2007, a new Rural Hospital Patient Safety Collaborative was implemented for the clinical segment of the Quality Improvement Strategic Plan. The state's 37 CAHs and 2 other rural hospitals participate in this collaborative. Additionally, the Flex Program, the QIO, SDAHO, and the state's three health systems are partners in the Patient Safety Collaborative. For this collaborative, the 39 rural hospitals completed the Agency for Healthcare Reach & Quality's (AHRQ) Hospital Survey on Patient Safety Culture during the summer of 2007. Based on the results of this survey, action plans were developed in early 2008 to address key issues. Since that time, quarterly conference calls are held to allow the hospital to present their progress on the action plans and to share tools they have developed increase patient safety.

In 2005, CAH Administrators on the QI Steering Committee attended a session on the Multi-State CAH Benchmarking Project at the Office of Rural Health Policy All Programs Meeting. After attending this session, the Administrators suggested a Process Improvement segment be added to the Flex Program QI Strategic Plan using this or a similar program. In 2006, South Dakota joined in the Multi-State Benchmarking Project that is coordinated by the Kansas Hospital Association. The Flex Program collaborates with SDAHO to manage the program for the CAHs. To start the program, data was collected from 20 South Dakota CAHs. Each year, more hospitals have been added to the project. Currently, 34 of the state's 37 CAHs participate in this project.

On the CAH Survey conducted during the spring of 2008, the hospitals were ask to list their greatest need for the next 3-5 years to improve quality of service. The most common responses to this question were health information technology implementation and staff training/education. Additionally, questions were asked regarding the benefits CAHs received from the QI Strategic Plan Activities. Regarding the Leadership Development Program, there were responses from 13

of the 20 CAHs that have participated. Of these 13, five thought the program provided a substantial benefit, three thought it provided a moderate benefit, four thought it provided a limited benefit, and one thought it provided no benefit. Regarding the Heartcare Collaborative, there were 30 responses. Of these 30, 11 reported receiving a substantial project benefit, 15 reported receiving a moderate benefit, and 4 reported receiving limited benefit. Regarding the Patient Safety Collaborative, there were 30 responses. Of these 30, 13 reported receiving a substantial benefit, 13 reported receiving a moderate benefit, 3 reported a limited benefit, and 1 reported no benefit. Regarding the benchmarking project, there were 28 responses. Of these 28, 10 reported receiving a substantial benefit, 13 reported receiving a moderate benefit, 3 reported a limited benefit, and 2 reported no benefit.

2. Future Plans

Goal: To increase performance improvement planning and programming in Critical Access Hospitals.

- Objective 1: To continue the CAH Leadership Development Program
    - Activity 1: The 3 CAHs in year one of the program and the 2 in year two advance to their next year of the program.
        - Outcome measure 1a: evaluations of the CAH department managers in the Leadership Program
    - Activity 2: Recruit up to 5 CAHs to participate in the three-year program
        - Outcome measure 2a: # of new CAHs enrolled in the program, participant evaluation, and all CAHs have an opportunity to participate in the program.
- Objective 2: To continue the Rural Hospital Patient Safety Collaborative
    - Activity 1: By November 30, 2008, complete follow-up AHRQ Hospital Survey on Patient Safety Culture
        - Outcome measure 1a: # of rural hospitals completing re-survey
        - Outcome measure 1b: Comparison of initial survey and re-survey to show progress gained from 2008 Action Plans
    - Activity 2: By January 31, 2009, rural hospitals develop Action Plans to address issues revealed by re-survey.
        - Outcome measure 2a: List of most common issues to be addressed in Action Plans
    - Activity 3: Will hold quarterly conference calls to share Action Plan progress and tools for increasing patient safety
        - Outcome measure 3a: # of hospitals and other collaborative partners participating on calls and list of tools shared
- Objective 3: To continue participation in the multi-state CAH Benchmarking Project
    - Activity 1: Enroll the non-participating CAHs into the project

    - Outcome measure 1a: By January 1, 2010, all South Dakota CAHs are participating
  - Activity 2: With the assistance of SDAHO, ensure CAHs submit data in a timely manner
    - Outcome measure 2a: Up to date data allows CAHs to measure their own progress and to compare their data to other CAHs.

- Objective 4: To continue the South Dakota CAH Quality Improvement Initiative Steering Committee

  - Activity 1: Will monitor the current QI Initiative programs
    - Outcome measure 1a: # of Steering Committee Meeting held each year to monitor programs
  - Activity 2: Will determine if projects need to be modified, phased out, or if new ones need to added to the QI Initiative
    - Outcome measure 2a: Specific modifications made to programs
    - Outcome measure 2b: Criteria for phasing out a project
    - Outcome measure 2c: Description and purpose of new projects, method or initiated new projects (i.e. statewide conference), and # of CAH and partners participating.

APPENDICIES

APPENDIX A

2008 South Dakota CAH Survey

CAH 2008

Default Section

* 1. Survey Respondent Information.

Hospital Name

Hospital City

Name of person completing survey

2. What is the ownership status of the hospital?

- ◯ Non-government, non-profit
- ◯ Government owned, county
- ◯ Government owned, city
- ◯ For profit

3. How would you characterize your organization?

- ◯ Stand alone acute care
- ◯ Acute care with a primary care clinic
- ◯ Acute care with long-term facility
- ◯ Acute care, primary care clinic, and long-term care facility

4. If you characterized your organization as a long-term care facility in question 3, what kind of long-term care facility? (check both if they apply)

- ☐ Nursing home
- ☐ Assisted living

5. How many licensed acute care beds do you have?

6. How many swing beds do you have?

7. Are you affiliated with a hospital/health system?

- ◯ Yes
- ◯ No

8. If you answered yes to question 5, please list the hospital/health system(s) which you are affiliated with.

9. If you answered yes to question 5, please indicate the type of affiliation you have.

- ◯ Owned
- ◯ Leased
- ◯ Managed
- ◯ Partnership

10. Rural hospitals face many pressures and issues. Please review each issue below and assess the degree of significance you feel is associated with that issue for your hospital. Mark the appropriate answer.

	No Problem	Minor Problem	Problem	Moderate Problem	Severe Problem
Physician workforce supply	◯	◯	◯	◯	◯
Nursing workforce supply	◯	◯	◯	◯	◯
Ancillary workforce supply (lab, x-ray, PT, etc)	◯	◯	◯	◯	◯
Maintaining access to primary care services	◯	◯	◯	◯	◯
Hospital reimbursement (Medicare)	◯	◯	◯	◯	◯
Hospital reimbursement (Medicaid)	◯	◯	◯	◯	◯
HIPAA compliance	◯	◯	◯	◯	◯
Access to capital	◯	◯	◯	◯	◯
Hospital staff training	◯	◯	◯	◯	◯
Hospital staff morale	◯	◯	◯	◯	◯
Life/Safety Code	◯	◯	◯	◯	◯
Rural community demographics	◯	◯	◯	◯	◯
Rural community economy	◯	◯	◯	◯	◯
Hosptial regulation (non-HIPAA)	◯	◯	◯	◯	◯
Maintaining access to EMS services	◯	◯	◯	◯	◯
Maintaining access to mental health services	◯	◯	◯	◯	◯
Impact of uninsured	◯	◯	◯	◯	◯
Impact of under-insured	◯	◯	◯	◯	◯
Maintaining quality of care	◯	◯	◯	◯	◯
Physical plant/building issues	◯	◯	◯	◯	◯
Ability to access telemedicine	◯	◯	◯	◯	◯
Ability to access technology	◯	◯	◯	◯	◯
Relationship with urban hospitals	◯	◯	◯	◯	◯
Relationship with urban clinics	◯	◯	◯	◯	◯

Relationship with other rural hospitals	○	○	○	○	○
Relationship with other rural clinics	○	○	○	○	○
Relationship with local clinic	○	○	○	○	○
Relationship with local/area public health	○	○	○	○	○
Relationship with local/area nursing home	○	○	○	○	○
Community support for the hospital	○	○	○	○	○
Indian Health Service reimbursement/relationships	○	○	○	○	○

11. From the above list please tell us which item is your number one concern at this time? Why?

12. Conversion to Critical Access Hospital status can bring forth a number of changes. Please review each subject below and assess how CAH conversion and the Flex program has impacted each of the following conditions. Mark the appropriate answer.

	Very Negative	Negative	Neutral	Positive	Very Positive
Financial Stability	○	○	○	○	○
Flexibility in staffing nurses in the hospital	○	○	○	○	○
Relationship with physicians	○	○	○	○	○
Service diversification/developing new services	○	○	○	○	○
Addressing local/area EMS issues	○	○	○	○	○
Addressing quality of care efforts	○	○	○	○	○
Physician Peer Review process	○	○	○	○	○
Access to Flex grants	○	○	○	○	○
Access to other federal or private foundation grants	○	○	○	○	○
Local fund raising	○	○	○	○	○
Access to capital	○	○	○	○	○
Recruitment/retention of physicians	○	○	○	○	○
Recruitment/retention of nurses	○	○	○	○	○
Recruitment/retention of ancillary staff	○	○	○	○	○
Public support of the hospital	○	○	○	○	○
Inpatient services	○	○	○	○	○
Network formation/relationships with tertiary partners	○	○	○	○	○
Network formation/relationship with other rural hospitals/CAHs	○	○	○	○	○
Telemedicine/Telehealth	○	○	○	○	○
Access to technical assistance (e.g., planning, community assessments, program information, community meetings, staff audits, etc.)	○	○	○	○	○
Overall hospital stability	○	○	○	○	○

13. From the list above please tell us which item has impacted your facility the most since conversion to a CAH. Why?

14. What was the estimated impact (to the nearest thousands of dollars) on the hospital's net income resulting from conversion to a CAH (or an Essential Access Community Hospital)at the end of the following time periods. (Please indicate either + of - for those years that apply).

Fiscal year of conversion	
First full year of conversion	
Second full year of conversion	
Third full year of conversion	
Fourth full year of conversion	
Fifth full year of conversion	

15. What was the hospital's net income/loss (to the nearest thousands of dollars) for the year prior to conversion to CAH/EACH?

16. Please list the benefit on the following FLEX programs.

	No Benefit	Limited Benefit	Moderate Benefit	Substantial Benefit	N/A
CAH RFP Program to fund local projects	○	○	○	○	○
Trauma Nurse Core Course Training	○	○	○	○	○
Trauma Receiving Center Reviews	○	○	○	○	○
CAH Leadership Development Program	○	○	○	○	○
Rural Hospital Patient Safety Project	○	○	○	○	○
CAH Performance Improvement Collaborative with the QIO	○	○	○	○	○
CAH Update Workshops	○	○	○	○	○
CAH Benchmarking Project	○	○	○	○	○
Health Professional Recruitment Incentive Program (HPRIP)	○	○	○	○	○
HOTT Health Workforce Career Planning Program	○	○	○	○	○
SDAHO Financial Forecasting Project	○	○	○	○	○

17. One of the federal goal areas of the FLEX Program is to develop networks between CAHs and other healthcare providers or other entities. This could include patient referral and transfer agreements, HIT, sharing of patient data, and other partnership projects.

Considering this FLEX Program goal, please tell us your needs for the next 3-5 years to improve network development.

18. Please tell us your needs for the next 3-5 years to improve quality of service.

19. Please tell us your needs for the next 3-5 years to improve emergency medical services.

20. Additional Comments?

APPENDIX B

Application for Designation Form

APPLICATION FOR DESIGNATION AS A
CRITICAL ACCESS HOSPITAL
(SOUTH DAKOTA CRITICAL ACCESS HOSPITAL PROGRAM)

I, _____, Administrator (or other officer of the hospital having the authority to bind the facility), certify that

(Name and Address of Applicant)
_____
_____
_____
_____

currently meets the following criteria:

A. Please Check the Appropriate Statements and Complete Required Sections

Criterion 1: Eligibility

_____ Is a nonprofit or public hospital and is located in either: 1) a county (or equivalent unit of local government) in a rural area as defined in section 1886(d)(2)(D) of the Social Security Act; or 2) any municipality of under 3,500 which is situated in a MSA but is more than 15 miles from a city of at least 50,000 population.

Criterion 2: Location relative to other facilities or necessary provider certification

_____ The CAH is located more than a 35-mile drive from a hospital or another CAH; or

_____ In the case of mountainous terrain or in areas with only secondary roads available, the CAH is located more than a 15-mile drive from a hospital or another CAH.

Note: Per the Code of Federal Regulations (42CFR485.610), effective January 1, 2006, the State of South Dakota cannot designate new CAHs using the necessary provider criteria.

Criterion 3: Member of a rural health network

(Please submit copies of agreements with application)

_____ Has signed written agreements with at least one Referral Hospital that is a member of the network pertaining to: 1) emergency and non-emergency patient referral and transfer; 2) the development and use of communications systems (if the network has in operation such a system); and 3) the provision of emergency and non-emergency transportation.

The Referral Hospital must demonstrate sufficient resources which include: at least three full time physicians on staff; demonstrated history of accepting patient referrals/transfers from the Applicant; and licensure as a general hospital.

Referral Hospital: _____
(Facility Name)

Address: _____
_____
_____
_____

_____ Has a signed written agreement describing the process for credentialing and quality assurance with at least one hospital that is a member of the network or with the South Dakota Foundation for Medical Care (QIO).

_____
(Facility or Entity Name)

Address: _____
_____
_____
_____

Criterion 4: Emergency services

_____ Makes available 24-hour emergency care services, seven days week, regardless of inpatient census (at least one physician on duty or on call at all times and available to the hospital on-site or by telephone within 20 minutes).

Criterion 5: Bed size

_____ Agrees to provide no more than 25 licensed beds.

_____ Agrees to provide no more than 15 swing beds.

Criterion 6: Staffing

_____ Agrees to maintain staffing levels of at least one registered nurse if the facility has at least one acute care patient, or one licensed nurse if the facility has no acute care patients.

Criterion 7: Acute care inpatient length of stay

_____ Agrees to or has a written policy in effect for providing inpatient care for a period that does not exceed, as determined on an annual, average basis, 96 hours per patient.

B. Supporting Documentation

Criterion 3: Member of a rural health network

Please indicate the number of Referral Hospital medical staff for each specialty listed.

Active Medical Staff

_____ Family Practice Physician
_____ General Internal Medicine
_____ General Surgeon
_____ OB/GYN
_____ Orthopod
_____ Radiologist

Emergency Room Staffing

_____ Physicians (on-site)
_____ Physicians (on-call)
_____ Other (Please specify)_____

Courtesy/Consulting Staff

_____	Pathologist	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Please complete the following.

_____ Number of referrals/transfers from the Applicant to the Referral Hospital in last fiscal year

_____ Referral Hospital market share of the county in which Applicant is located

Please complete the following pertaining to the Applicant.

_____ Number of licensed acute care beds (current)
_____ Number of swing-beds (current)
_____ Number of licensed beds (CAH) – may not exceed 25 beds
_____ Number of swing beds (CAH)

Activity	Completed (Date)	Planned (Date)	Not Planned
Financial feasibility study for CAH			
Medical Staff Planning/ Education			
Hospital Board Planning/Education			
Community Planning/ Education			

_____

Signature

_____

Date

APPENDIX C

Applicable Federal and State Program Laws and Regulations

[Code of Federal Regulations]
[Title 42, Volume 4]
[Revised as of October 1, 2007]
From the U.S. Government Printing Office via GPO Access
[**CITE**: **42CFR485**]

[Page 640-653]

TITLE 42--PUBLIC HEALTH

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 485_CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS--Table of Contents

Subpart F_Conditions of Participation: Critical Access Hospitals (CAHs)

Source: 58 FR 30671, May 26, 1993, unless otherwise noted.

Sec. 485.601 Basis and scope.

(a) Statutory basis. This **subpart** is based on section 1820 of the Act which sets forth the conditions for designating certain hospitals as CAHs.
(b) Scope. This **subpart** sets forth the conditions that a hospital must meet to be designated as a CAH.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.602 Definitions.

As used in this **subpart**, unless the context indicates otherwise:
Direct services means services provided by employed staff of the CAH, not services provided through arrangements or agreements.

[59 FR 45403, Sept. 1, 1994, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.603 Rural health network.

A rural health network is an organization that meets the following specifications:
(a) It includes--
(1) At least one hospital that the State has designated or plans to designate as a CAH; and
(2) At least one hospital that furnishes acute care services.
(b) The members of the organization have entered into agreements regarding--
(1) Patient referral and transfer;
(2) The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data; and
(3) The provision of emergency and nonemergency transportation among members.

(c) Each CAH has an agreement with respect to credentialing and quality assurance with at least--

(1) One hospital that is a member of the network when applicable;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46035, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

Sec. 485.604 Personnel qualifications.

Staff that furnish services in a CAH must meet the applicable requirements of this section.

(a) Clinical nurse specialist. A clinical nurse specialist must be a person who performs the services of a clinical nurse specialist as authorized by the State, in accordance with State law or the State regulatory mechanism provided by State law.

(b) Nurse practitioner. A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:

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(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has successfully completed a 1 academic year program that--

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (a)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

(c) Physician assistant. A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

(2) Has satisfactorily completed a program for preparing physician assistants that--

(i) Was at least one academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for

preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.606 Designation and certification of CAHs.

(a) Criteria for State designation. (1) A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in this **subpart F**.

(2) The State must not deny any hospital that is otherwise eligible for designation as a CAH under this paragraph (a) solely because the hospital has entered into an agreement under which the hospital may provide posthospital SNF care as described in Sec. 482.66 of this chapter.

(b) Criteria for CMS certification. CMS certifies a facility as a CAH if--

(1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in this Part and all other applicable requirements for participation in Part 489 of this chapter.

(2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997, and is otherwise eligible to be designated as a CAH by the State under the rules in this **subpart**.

[62 FR 46036, Aug. 29, 1997, as amended at 63 FR 26359, May 12, 1998]

Sec. 485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) Standard: Compliance with Federal laws and regulations. The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

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(b) Standard: Compliance with State and local laws and regulations. All patient care services are furnished in accordance with applicable State and local laws and regulations.

(c) Standard: Licensure of CAH. The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

(d) Standard: Licensure, certification or registration of personnel. Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.610 Condition of participation: Status and location.

(a) Standard: Status. The facility is--

(1) A currently participating hospital that meets all conditions of participation set forth in this **subpart**;

(2) A recently closed facility, provided that the facility--

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this **subpart** as of the effective date of its designation; or

(3) A health clinic or a health center (as defined by the State) that--

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this **subpart**.

(b) Standard: Location in a rural area or treatment as rural. The CAH meets the requirements of either paragraph (b)(1) or (b)(2) or (b)(3) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under Sec. 412.64(b), excluding paragraph (b)(3) of this chapter;

(ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under Sec. 412.230(e) of this chapter, and is not among a group of hospitals that have been redesignated to an adjacent urban area under Sec. 412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with Sec. 412.103 of this chapter.

(3) Effective only for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003.

(c) Standard: Location relative to other facilities or necessary provider certification. The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

(d) Standard: Relocation of CAHs with a necessary provider designation. A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the

requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location--

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(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii) Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in Sec. 489.52(b)(3).

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 66 FR 39938, Aug. 1, 2001; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 70 FR 47490, Aug. 12, 2005; 71 FR 48143, Aug. 18, 2006]

Sec. 485.612 Condition of participation: Compliance with hospital requirements at the time of application.

Except for recently closed facilities as described in Sec. 485.610(a)(2), or health clinics or health centers as described in Sec. 485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

[66 FR 32196, June 13, 2001]

Sec. 485.616 Condition of participation: Agreements.

(a) Standard: Agreements with network hospitals. In the case of a CAH that is a member of a rural health network as defined in Sec. 485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for--

(1) Patient referral and transfer;

(2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and

(3) The provision of emergency and nonemergency transportation between the facility and the hospital.

(b) Standard: Agreements for credentialing and quality assurance. Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least--

(1) One hospital that is a member of the network;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[62 FR 46036, Aug. 29, 1997]

Sec. 485.618 Condition of participation: Emergency services.

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

(a) Standard: Availability. Emergency services are available on a 24-hours a day basis.

(b) Standard: Equipment, supplies, and medication. Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

(1) Drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

(2) Equipment and supplies commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

(c) Standard: Blood and blood products. The facility provides, either directly or under arrangements, the following:

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

(2) Blood storage facilities that meet the requirements of 42 CFR part 493, **subpart** K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement,

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the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

(d) Standard: Personnel. (1) Except as specified in paragraph (d)(3) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on site within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse with training and experience in emergency care can be utilized to conduct specific medical screening examinations only if--

(i) The registered nurse is on site and immediately available at the CAH when a patient requests medical care; and

(ii) The nature of the patient's request for medical care is within the scope of practice of a registered nurse and consistent with applicable State laws and the CAH's bylaws or rules and regulations.

(3) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if--

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural healthcare plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(3)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(4) The request, as specified in paragraph(d)(3)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

(e) Standard: Coordination with emergency response systems. The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients,

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and refer patients to the CAH or other appropriate locations for treatment.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 41544, July 30, 1999; 67 FR 80041, Dec. 31, 2002; 69 FR 49271, Aug. 11, 2004; 71 FR 68230, Nov. 24, 2006]

Sec. 485.620 Condition of participation: Number of beds and length of stay.

(a) Standard: Number of beds. Except as permitted for CAHs having distinct part units under Sec. 485.647, the CAH maintains no more than 25 inpatient beds after January 1, 2004, that can be used for either inpatient or swing-bed services.

(b) Standard: Length of stay. The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004]

Sec. 485.623 Condition of participation: Physical plant and environment.

(a) Standard: Construction. The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) Standard: Maintenance. The CAH has housekeeping and preventive maintenance programs to ensure that--

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

(2) There is proper routine storage and prompt disposal of trash;

(3) Drugs and biologicals are appropriately stored;

(4) The premises are clean and orderly; and

(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

(c) Standard: Emergency procedures. The CAH assures the safety of patients in non-medical emergencies by--

(1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;

(3) Providing for an emergency fuel and water supply; and

(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

(d) Standard: Life safety from fire. (1) Except as otherwise provided in this section--

(i) The CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101 ^[reg] 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal--register/code--of--federal--regulations/ibr--locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal

Register to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.

(2) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

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(4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

(5) Beginning March 13, 2006, a critical access hospital must be in compliance with Chapter 9.2.9, Emergency Lighting.

(6) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to critical access hospitals.

(7) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a critical access hospital may install alcohol-based hand rub dispensers in its facility if--

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00-1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00-1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269; and

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46036, 46037, Aug. 29, 1997; 68 FR 1387, Jan. 10, 2003; 69 FR 49271, Aug. 11, 2004; 70 FR 15239, Mar. 25, 2005; 71 FR 55341, Sept. 22, 2006]

Sec. 485.627 Condition of participation: Organizational structure.

(a) Standard: Governing body or responsible individual. The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH's total operation and for ensuring that those policies are

administered so as to provide quality health care in a safe environment.

(b) Standard: Disclosure. The CAH discloses the names and addresses of--

(1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with **subpart** C of part 420 of this chapter;

(2) The person principally responsible for the operation of the CAH; and

(3) The person responsible for medical direction.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.631 Condition of participation: Staffing and staff responsibilities.

(a) Standard: Staffing--(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the CAH.

(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

(b) Standard: Responsibilities of the doctor of medicine or osteopathy. (1) The doctor of medicine or osteopathy--

(i) Provides medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff;

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(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH's patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

(iv) Periodically reviews and signs the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants.

(v) Periodically, but not less than every 2 weeks, reviews and signs a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants according to the policies of the CAH and according to current standards of practice where State law requires record reviews or co-signatures, or both, by a collaborating physician.

(vi) Is not required to review and sign outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants where State law does

not require record reviews or co-signatures, or both, by a collaborating physician.

(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the latest site visit.

(c) Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities. (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff--

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 70 FR 68728, Nov. 10, 2005]

Sec. 485.635 Condition of participation: Provision of services.

(a) Standard: Patient care policies. (1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of Sec. 485.631(a)(1); at least one member is not a member of the CAH staff.

(3) The policies include the following: (i) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

(ii) Policies and procedures for emergency medical services.

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral,

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the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of Sec. 483.25(i) is met with respect to inpatients receiving posthospital SNF care.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

(b) Standard: Direct services--(1) General. The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(2) Laboratory services. The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose:

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

(3) Radiology services. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

(4) Emergency procedures. In accordance with the requirements of Sec. 485.618, the CAH provides as direct services medical emergency procedures as a first response to common life-threatening injuries and acute illness.

(c) Standard: Services provided through agreements or arrangements. (1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including--

(i) Inpatient hospital care;

(ii) Services of doctors of medicine or osteopathy; and

(iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH.

(iv) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

(4) The person principally responsible for the operation of the CAH under Sec. 485.627(b)(2) of this chapter is also responsible for the following:

(i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.

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(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

(d) Standard: Nursing services. Nursing services must meet the needs of patients.

(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

(4) A nursing care plan must be developed and kept current for each inpatient.

[58 FR 30671, May 26, 1993; 58 FR 49935, Sept. 24, 1993, as amended at 59 FR 45403, Sept. 1, 1994; 62 FR 46037, Aug. 29, 1997]

Sec. 485.638 Conditions of participation: Clinical records.

(a) Standard: Records system--(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable--

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the

health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) Standard: Protection of record information--(1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) Standard: Retention of records. The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.639 Condition of participation: Surgical services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

(a) Designation of qualified practitioners. The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance

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with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by--

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

(b) Anesthetic risk and evaluation. (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

(c) Administration of anesthesia. The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with

its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only--

(i) A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

(v) A certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as described in Sec. Sec. 413.85 or 413.86 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(d) Discharge. All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(e) Standard: State exemption. (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[60 FR 45851, Sept. 1, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 66 FR 39938, Aug. 1, 2001; 66 FR 56769, Nov. 13, 2001]

Sec. 485.641 Condition of participation: Periodic evaluation and quality assurance review.

(a) Standard: Periodic evaluation--(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of--

(i) The utilization of CAH services, including at least the number of patients served and the volume of services;

(ii) A representative sample of both active and closed clinical records; and

(iii) The CAH's health care policies.

(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

(b) Standard: Quality assurance. The CAH has an effective quality assurance

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program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that--

(1) All patient care services and other services affecting patient health and safety, are evaluated;

(2) Nosocomial infections and medication therapy are evaluated;

(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by--

(i) One hospital that is a member of the network, when applicable;

(ii) One QIO or equivalent entity; or

(iii) One other appropriate and qualified entity identified in the State rural health care plan; and

(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

(iii) The CAH documents the outcome of all remedial action.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

Sec. 485.643 Condition of participation: Organ, tissue, and eye procurement.

The CAH must have and implement written protocols that:

(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated

requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(**f**) For purposes of these standards, the term ``organ'' means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

[65 FR 47110, Aug. 1, 2000, as amended at 66 FR 39938, Aug. 1, 2001]

Sec. 485.645 Special requirements for CAH providers of long-term care services (``swing-beds'')

A CAH must meet the following requirements in order to be granted an approval from CMS to provided post-hospital SNF care, as specified in Sec. 409.30 of this chapter, and to be paid

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for SNF-level services, in accordance with paragraph (c) of this section.

(a) Eligibility. A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by CMS under Sec. 485.606(b) of this **subpart**; and

(2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

(b) Facilities participating as rural primary care hospitals (RPCHs) on September 30, 1997. These facilities must meet the following requirements:

(1) Notwithstanding paragraph (a) of this section, a CAH that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions and limitations that were applicable at the time those approvals were granted.

(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

(c) Payment. Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with Sec. 413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the

payment provisions in Sec. 413.114 of this chapter.

(d) SNF services. The CAH is substantially in compliance with the following SNF requirements contained in **subpart** B of part 483 of this chapter:

(1) Residents rights (Sec. 483.10(b)(3) through (b)(6), (d) (e), (h), (i), (j)(1)(vii) and (viii), (l), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (Sec. 483.12(a) of this chapter).

(3) Resident behavior and facility practices (Sec. 483.13 of this chapter).

(4) Patient activities (Sec. 483.15(**f**) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of Sec. 485.15(**f**)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (Sec. 483.15(g) of this chapter).

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (Sec. 483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under Sec. 483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in Sec. 413.343(b) of this chapter).

(7) Specialized rehabilitative services (Sec. 483.45 of this chapter).

(8) Dental services (Sec. 483.55 of this chapter).

(9) Nutrition (Sec. 483.25(i) of this chapter).

[63 FR 26359, May 12, 1998 as amended at 64 FR 41544, July 30, 1999; 67 FR 50120, Aug. 1, 2002; 69 FR 49272, Aug. 11, 2004]

Sec. 485.647 Condition of participation: psychiatric and rehabilitation distinct part units.

(a) Conditions. (1) If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of Sec. 412.25(a)(2) through (**f**) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of Sec. 412.27 of Part 412 of this chapter for excluded psychiatric units.

(2) If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the

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hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of Sec. 412.25(a)(2) through (**f**) of Part 412 of this chapter for hospital units excluded from the prospective payments systems, and the additional requirements of Sec. Sec. 412.29 and Sec. 412.30 of Part 412 of this chapter related specifically to rehabilitation units.

(b) Eligibility requirements. (1) To be eligible to receive Medicare

payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in Sec. 485.620(a).

(3) The average annual 96-hour length of stay requirement specified under Sec. 485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in Sec. 485.620.

[69 FR 49272, Aug. 11, 2004]

SOUTH DAKOTA ADMINISTRATIVE RULE
Article 44:04

Note: The following are only excerpts from Article 44:04 that pertain to Critical Access Hospitals.

44:04:01:01. Definitions. Terms defined in SDCL 34-12-1.1 have the same meaning in this article. In addition, terms used in this article mean:

(11) "Department," the South Dakota Department of Health;

(17) "Distinct part," an identifiable unit, such as an entire ward or contiguous wards, wing, floor, or building, which is licensed at a specific level. It consists of all beds and related facilities in the unit;

(18) "Emergency care," professional health services immediately necessary to preserve life or stabilize health due to the sudden, severe, and unforeseen onset of illness or accidental bodily injury;

(21) "Facility," the place of business used to provide health care for patients or residents;

(30) "Licensed health professional," a physician; physician's assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; nurse; nursing facility administrator; dietitian; pharmacist; respiratory therapist; or social worker who holds a current license to practice in South Dakota;

(31) "Medical staff," an organized staff composed of practitioners that operates under bylaws approved by the governing body and which is responsible for reviewing the qualifications of practitioners applying for clinical privileges and for the provision of medical care to patients and residents in a health care facility;

(34) "Nurse," a registered nurse or a licensed practical nurse who holds a current license to practice in South Dakota pursuant to SDCL chapter 36-9;

(38) "Patient," a person with a valid order by a practitioner for diagnostic or treatment services in a hospital, specialized hospital, critical access hospital, swingbed, ambulatory surgery center, or chemical dependency treatment facility;

(46) "Referral hospital," a general hospital with medical personnel qualified to receive emergency and nonemergency patient transfers from a critical access hospital, which has sufficient resources to provide consultation to a critical access hospital in the areas of clinical protocols, quality assurance, utilization review, staff inservice, and business consultation;

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 15 SDR 155, effective April 20, 1989; 17 SDR 122, effective February 24, 1991; 19 SDR 95, effective January 7, 1993; 21 SDR 118, effective January 2, 1995; 22 SDR 70, effective

November 19, 1995; 24 SDR 90, effective January 4, 1998; 26 SDR 96, effective January 23, 2000; 27 SDR 59, effective December 17, 2000; 28 SDR 83, effective December 16, 2001; 29 SDR 81, effective December 11, 2002; 30 SDR 84, effective December 4, 2003; 31 SDR 62, effective November 7, 2004; 32 SDR 128, effective January 30, 2006.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13, 34-12-32.

44:04:01:02. Licensure of facilities by classification. Applications for licensure of a health care facility must set out the classification being applied for. Any license issued shall denote the classification and the facility address on the face of the license. The license shall include each facility address at which services licensed under this chapter are provided. A critical access hospital must first receive notice of eligibility for licensure from the secretary of health. A facility must comply only with those chapters in this article that apply to the classification of license issued. The most current license issued by the department must be posted on the premises of the facility in a place conspicuous to the public. Each facility address shall show a current license. The license certificate remains the property of the department. Facility classifications in addition to those defined in SDCL 34-12-1.1 are as follows:

(1) General hospital;
(2) Specialized hospital; and
(3) Hospice facility.

Source: SL 1975, ch 16, § 1; 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 27 SDR 59, effective December 17, 2000.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-7, 34-12-13.

44:04:01:02.01. Annual license fees for health care facilities. The annual license fees for health care facilities, which includes up to two amendment applications of the license during the licensure year, are as follows:

(1) For an ambulatory surgery center, $100;
(2) For a chemical dependency treatment facility, $100 plus $3 for each bed licensed;
(3) For a hospital, $100 plus $3 for each bed licensed, except that the fee for each bed for a hospital qualifying for exemption pursuant to SDCL 34-12-16 is $2;
(4) For a maternity home, $100 plus $3 for each bed licensed;
(5) For a nursing facility, $100 plus $3 for each bed licensed;
(6) For an assisted living center, $100 plus $3 for each bed licensed;
(7) For a critical access hospital, $100 plus $3 for each bed licensed;
(8) For a hospice facility, $100 plus $3 for each bed licensed; and
(9) For an adult foster care home, no fee.

Source: 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 30 SDR 84, effective December 4, 2003.

General Authority: SDCL 34-12-6.
Law Implemented: SDCL 34-12-6.

44:04:01:02.02. License amendment application fee. The amendment application fees for each license change in excess of two during the licensure year are as follows:

(1) For an ambulatory surgery center, $20;
(2) For a chemical dependency treatment facility, $20;
(3) For a hospital, $20;
(4) For a maternity home, $20;
(5) For a nursing facility, $20;
(6) For an assisted living center, $20;
(7) For a critical access hospital, $20;
(8) For a hospice facility, $20; and
(9) For an adult foster care home, no fee.

Source: 26 SDR 96, effective January 23, 2000.
General Authority: SDCL 34-12-6.
Law Implemented: SDCL 34-12-6.

44:04:01:04. Bed capacity. The department shall establish the bed capacity of each facility pursuant to the physical plant and space provisions of this article. The patient or resident census must not exceed the bed capacity for which the facility is licensed. A request by the facility for an adjustment in bed capacity because of change of purpose or construction must be approved by the department before any changes are made. A critical access hospital (CAH) may license no more than 25 beds. A CAH may establish a distinct part unit (e.g., psychiatric or rehabilitation) that meets requirements for such beds as established for a short-term, general hospital. Those beds may not count toward the CAH bed limit, and the total number in each distinct part unit may not exceed ten.

Source: SL 1975, ch 16, § 1; 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 30 SDR 84, effective December 4, 2003; 31 SDR 62, effective November 7, 2004.
General Authority: SDCL 34-12-13.
Law Implemented: SDCL 34-12-7, 34-12-13.

44:04:01:05. Restrictions on acceptance of patients or residents. A facility shall accept patients or residents in accordance with the following restrictions:

(7) A critical access hospital may provide inpatient acute care up to an annual average length of stay of 96 hours; and

Source: 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective

November 19, 1995; 24 SDR 90, effective January 4, 1998; 26 SDR 96, effective January 23, 2000; 27 SDR 59, effective December 17, 2000.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:01:08. Modifications. Modifications to standards provided in this article may be approved by the department for an assisted living center with a licensed bed capacity of 16 or less or an adult foster care home if the health and safety of the residents are not jeopardized.

Modifications to the staffing requirements provided in § 44:04:03:02 or 44:04:06:08 may be approved by the department for licensed facilities which are physically combined and jointly operated if:

(1) A hospital or critical access hospital and nursing facility are co-located and the nursing facility has a licensed bed capacity of 16 or less or the hospital has an acute care patient daily census of less than five;

(2) A hospital or a critical access hospital and assisted living center are co-located; or

(3) A nursing facility and assisted living center are co-located.

The health and safety of the patients or residents in either facility must not be jeopardized.

Modifications to the staffing requirements in this article may be approved by the department for a critical access hospital if there are no acute care or swing bed patients present.

Modifications specified by this section may be requested by the health care facility. Any modifications must be approved in writing by the department. The approval letter must specify the modifications permitted and any limitations pertaining to the modifications.

Source: 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 29 SDR 81, effective December 11, 2002.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:04:15. Transfer agreements. Each specialized hospital and critical access hospital must have in effect a transfer agreement with one or more hospitals to provide services not available on site. The agreement must provide for an interchange of medical and other necessary information

Source: Transferred from § 44:04:04:07, 17 SDR 122, effective February 24, 1991; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:05:03. Emergency physician coverage for hospitals and nursing facilities. A patient's or resident's physician shall arrange for the care of the patient or resident by an alternate physician during the physician's unavailability. A hospital must have one or more physicians on duty or call at all times and available to the hospital on-site or by telephone within 20 minutes to give necessary orders or medical care to patients in case of emergency.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 27 SDR 59, effective December 17, 2000.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:05:07. Medical director required. A critical access hospital and a nursing facility must appoint a physician licensed in South Dakota to serve as a medical director. The medical director shall assure physician services are provided only by qualified caregivers.

Source: 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:06:08. Nursing service staffing for hospitals. All hospitals must maintain a sufficient number of registered nurses and other qualified nursing personnel on duty at all times to provide supervision of and nursing care for all patients. A registered nurse must be designated as charge nurse for each nursing care unit at all times except that a critical access hospital is required to staff with a registered nurse only when there are acute care patients present. A critical access hospital is required to staff with a licensed nurse when there are only swing bed patients present. Written staffing patterns must be developed for each patient care unit, including surgical and obstetrical suites, emergency services, special care units, and other services. Registered nurses must be in charge of the operating room, function as supervisory nurse in the operating room, be in attendance at all deliveries of obstetrical patients, supervise obstetrical nursing service, and supervise the nursing care of newborn infants.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:11:11. Eligibility to offer swing-bed services. A hospital with less than 100 staffed beds may offer swing-bed services after obtaining approval from the department pursuant to § 44:04:11:11.01. A hospital with less than 50 staffed beds may not designate more than one-half of its staffed beds as swing beds, but a hospital with less than 50 licensed beds may designate up to one-half of its licensed beds as swing beds. A critical access hospital may have no more than 15 swing beds. A hospital with 50 to 99 staffed beds, inclusive, may not designate more than 10 beds as swing beds. A hospital which subsequently exceeds 99 staffed beds may not offer swing-bed services. For purposes of this section and § 44:04:11:11.01, staffed beds are inpatient beds

utilized and staffed for by the hospital, exclusive of beds for newborn, obstetrical delivery, intensive care, coronary care, and any psychiatric or rehabilitation unit excluded from the Medicare prospective payment system, except during a catastrophe, such as a disaster or epidemic, to which the hospital responds.

Source: 14 SDR 81, effective December 10, 1987; 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 27 SDR 59, effective December 17, 2000; 29 SDR 81, effective December 11, 2002; 30 SDR 84, effective December 4, 2003.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:11:11.01. Application for approval to offer swing-bed services. A hospital may not offer swing-bed services without first applying in writing to the department for approval. The application must contain the following:

(1) The effective date the swing-bed services will begin;

(2) Designation of the bed category for which the hospital is requesting approval to offer swing-bed services, either a critical access hospital, not more than 49 staffed beds, or greater than 49 staffed beds and fewer than 100 staffed beds;

(3) The number of staffed beds which will be designated as swing beds;

(4) Evidence of the hospital's ability to comply with the provisions of § 44:04:11:12; and

(5) Written assurance that the hospital will operate within the bed category it has designated and will not operate more than the number of swing beds designated on the face of the license.

The department shall denote the number of designated swing beds on the face of the license. A hospital may not change the number of designated swing beds or the designated bed category without first applying to the department for approval in accordance with this section.

Source: 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000

General Authority: SDCL 34-12-5, 34-12-13.

Law Implemented: SDCL 34-12-5, 34-12-13.

44:04:11:12. Patient care requirements for swing-bed services. Hospital and critical access hospital swing-bed services must provide nursing and related care services to meet patients' care needs at all times. Patient care services must include at least the following:

(1) Patient rights as stated in §§ 44:04:17:02(1),(5),(6),(7),(8), 44:04:17:03(1), 44:04:17:07, 44:04:17:08(1),(2),(7),(9), 44:04:17:09(3),(4),(5), 44:04:17:12, and 44:04:17:14;

(2) Specialized rehabilitative services needed by patients to improve and maintain functioning. Specialized rehabilitative services may include physical therapy, speech pathology and audiology, and occupational therapy; and the services must be provided by the hospital or arranged for by written agreement with qualified personnel;

(3) Dental services for routine and emergency dental care;

(4) Social services as stated in § 44:04:12:05;

(5) Patient activities as stated in § 44:04:12:02;

(6) Discharge planning services to ensure that patients have a planned program of continuing care which meets post-discharge needs. The hospital must have written policies for the discharge planning process and must comply with § 44:04:04:17; and

(7) Comprehensive assessment to assist with the development of a comprehensive care plan.

Source: 14 SDR 81, effective December 10, 1987; 19 SDR 95, effective January 7, 1993; 22 SDR 70, effective November 19, 1995; 29 SDR 81, effective December 11, 2002; 32 SDR 128, effective January 30, 2006.
General Authority: SDCL 34-12-13.
Law Implemented: SDCL 34-12-13.

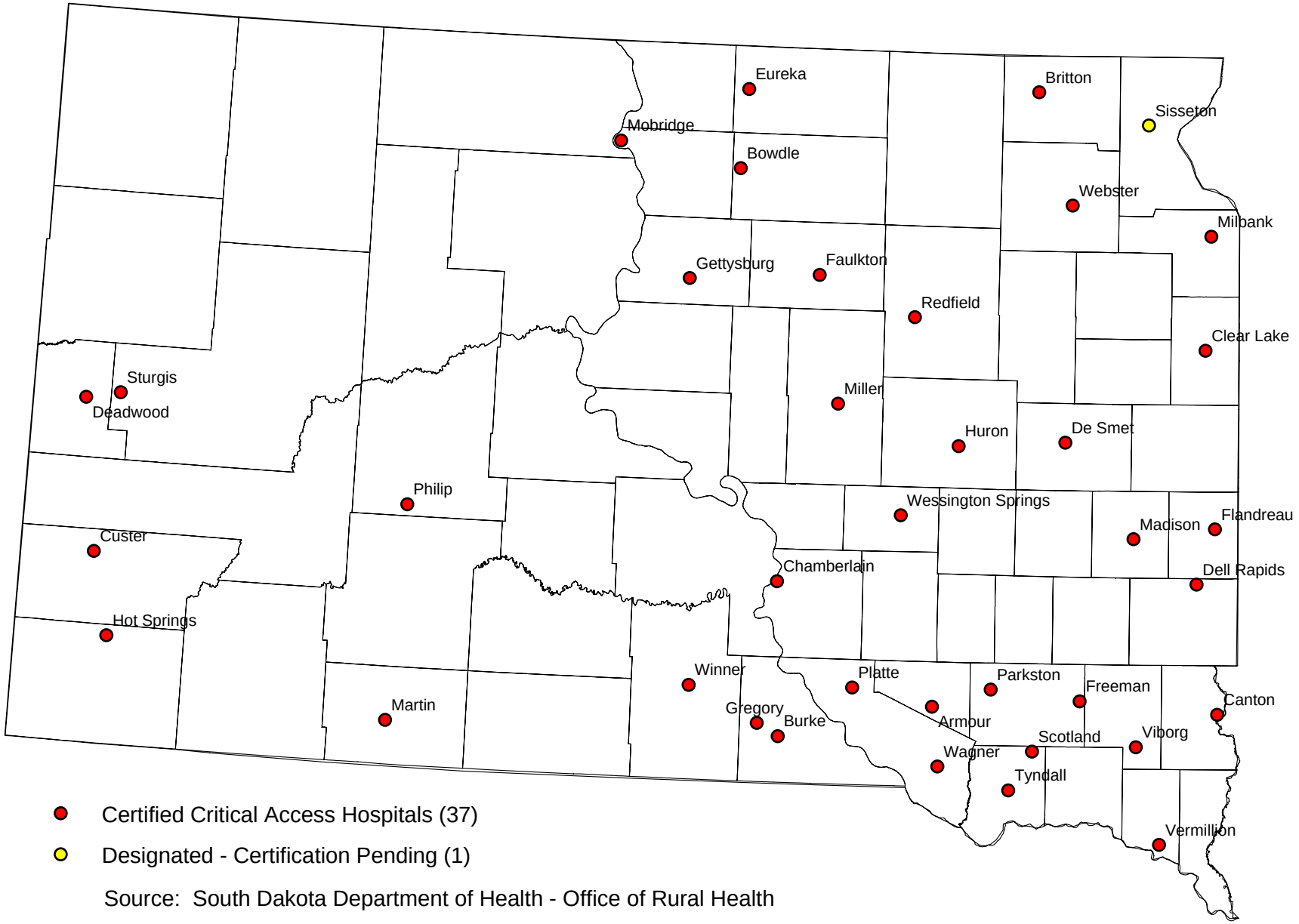
44:04:12:01. Supportive services. Each nursing facility, assisted living center, hospital accepting long-term care patients, and hospital and critical access hospital with swing beds must provide supportive services that comply with §§ 44:04:12:02 to 44:04:12:05, inclusive.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 30 SDR 84, effective December 4, 2003.
General Authority: SDCL 34-12-13.
Law Implemented: SDCL 34-12-13.

APPENDIX D

South Dakota CAH Map

South Dakota Critical Access Hospitals
November 1, 2008



- Certified Critical Access Hospitals (37)
- Designated - Certification Pending (1)

Source: South Dakota Department of Health - Office of Rural Health